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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,958	09/15/2005	Barbara Ensoli	11340-007-999	1299

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EXAMINER	
KINSEY WHITE, NICOLE ERIN	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
03/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/549,958	ENSOLI, BARBARA	
	Examiner	Art Unit	
	NICOLE KINSEY WHITE	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *76-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *76-86* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/15/2005 & 9/29/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group II (a method for treating a tumor or blocking the growth of a tumor, new claims 76-86) in the reply filed on February 8, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

The disclosure is objected to because of the following informalities: In the brief description of the figures, Figure 1 should recite "panels A and B" instead of "A e B."

Appropriate correction is required.

The use of a trademark has been noted in this application (see, for example, page 7). A trademark should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 76-79 and 81-86 are rejected under 35 U.S.C. 102(b) as being anticipated by Weichold et al (WO 00/33654).

The claims are drawn to a method for treating a tumor or blocking cell migration or invasion, comprising administering indinavir at a daily dose of 1200 mg to a human subject having a tumor or in need of said blocking.

Weichold et al. discloses using HIV protease inhibitors to treat diseases and conditions including cancer (see page 23, lines 22-25). Weichold et al. states that cancer patients, or persons at increased risk of developing cancer, will be administered at least one protease inhibitor to boost and/or modulate the immune system, thereby resulting in effective treatment and/or prophylaxis of cancers (see page 33, lines 7-17). Weichold et al. further states that such protease inhibitor can be used by itself or in conjunction with other anti-cancer treatments or prophylaxis, e.g., chemotherapeutics, radiation, other immune modulators, cytokines, and immunotherapeutics. Cancers that are treatable and/or preventable include breast, prostate, liver, bladder, lung, esophageal, stomach, skin, pancreatic, brain, uterine, colon, brain, head and neck, and ovarian cancer (see page 33, lines 21-26).

The inhibitors of Weichold et al. include, but are not limited to, Saquinavir, Ritonavir, Indinavir, Nelfinavir, and Amprenavir (see page 25, lines 6-9). The HIV protease inhibitors can be administered orally, parenterally, topically or by inhalation. The term parenteral as used herein includes intravenous, intraperitoneal, intramuscular, subcutaneous, rectal or vaginal administration. The dosage is preferable 0.5 to 20 mg/kg per day for oral or parenteral administration (see page 29, lines 12-24). For a human with a mass of 75 kg, this translates to a range of 37.5 mg to 1500 mg of HIV protease inhibitor per day.

Weichold et al. found that HIV protease inhibitors have anti-inflammatory effects that influence endothelial cell activation and proliferation, thus inhibiting mechanisms that also can lead to tumor neovascularization (i.e., cell migration and invasion) (see page 71, lines 3-12 and Figures 15-18). In addition, Weichold et al. found that HIV protease inhibitors inhibited *in vitro* and *in vivo* tumor formation by Kaposi sarcoma (KS) derived cells and leukemia-derived cells in immune deficient BNX-mice and in immune competent BALB\c mice (see Figures 27a-b), indicating that the anti-neoplastic effect of the HIV protease inhibitor is independent of tumor-specific immune responses (see page 76, lines 4-20).

Thus, Weichold et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 80 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weichold et al (WO 00/33654) as applied to claims 76-79 and 81-86 above.

The claim is drawn to a method for treating a tumor or blocking cell migration or invasion, comprising administering indinavir at a daily dose of 1200 mg to a human subject having a tumor or in need of said blocking, wherein the method further comprises administering to said human subject nelfinavir.

The teachings of Weichold et al. are discussed above. Weichold et al. does not specifically teach administering a composition comprising both indinavir and nelfinavir. However, Weichold et al. does teach that each protease inhibitor can be used to treat conditions such as cancer, tumors and neovascularization.

It would have been obvious to one of skill in the art to combine the indinavir and nelfinavir to treat cancer or tumors as taught by Weichold et al.

One of skill in the art would have been motivated to administer a combination of agents, such as indinavir and nelfinavir because both are useful for treating cancer or tumors as taught by Weichold et al., and one of ordinary skill in the art would have had a reasonable expectation of success that the combination treatment would result in the

intended use of treating cancer or tumors. A multi-drug treatment approach to tumor therapy is expected to be more aggressive.

Further, the courts have said: "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose . . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). In this case, applicants are combining two known HIV protease inhibitors which are taught to be useful for treating cancer and/or tumors.

Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White, PhD/
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648